

### REMARKS

Claims 1-12 are pending in this application. Claims 1-9, and 11-12 stand rejected for the reasons indicated in the Office Action. In response, claims 1-3, 9 and 10 have been amended, and claims 23-32 stand withdrawn. No new matter is added by these amendments. Entry of these amendments is hereby requested.

**With Respect to New Claims 23-32, Paragraphs 2 and 3 of the Office Action:**

Claims 23-32 have been withdrawn for the reasons indicated in paragraphs 2 and 3 of the Office Action, the Patent and Trademark Office indicating that the method described in claims 23-32 is patentably distinct. Claim 23 is merely previously present claim 10 which was not found to have any reasons for being unpatentable. A restriction requirement was already issued in the present application, dated March 28, 2002, and claim 10 was found NOT to be patentably distinct from the examined claims. For convenience, the limitations of claim 23 are given as follows:

Previously presented claim 1:

A method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material comprising:

- a) providing living bacteria which are modified to produce a first detectable signal;
- b) placing the modified living bacteria on a first side of the material being evaluated;
- and
- c) detecting whether the first signal is present on a second side of the material or within the material;

where absence of the first signal on the second side of the material or within the material indicates that the modified living bacteria have not passed through or around the material and where presence of the first signal on the second side of the material or within the material indicates that the modified living bacteria have passed through or around the material;

Previously presented claim 3:

where the modified living bacteria are modified to produce a second detectable signal, and where the method additionally comprises detecting whether the second signal is present on the second side of the material or within the material;

where absence of the second signal on the second side of the material or within the material indicates that the modified living bacteria have not passed through or around the material and where presence of the second signal on the second side of the material or within

the material indicates that the modified living bacteria have passed through or around the material;

Previously presented claim 10:

where placing the modified living bacteria on a first side of the material being evaluated comprises placing the modified living bacteria in the center of a hollowed out, extracted natural tooth where the root end of the tooth is sealed with the material, and then placing the root end of the tooth in a test medium; and

where detecting whether the first signal is present on a second side of the material or within the material comprises detecting the first signal in the test medium or within the material.

Hence, the Patent and Trademark Office cannot now declare this subject matter patentably distinct. Therefore, the Applicant hereby requests removal of the rejoinder of claims 23-32 as both not patentably distinct, as already examined and as allowable.

**With Respect to the Rejections under 35 U.S.C. §102(b), Paragraph 6 of the Outstanding Office Action:**

Claims 1, 2, 4, 7 and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by Loessner et al. for the reasons discussed in paragraph 6 of the Office Action. Loessner et al. discloses a method of detecting bacterial contamination of food by *Listeria monocytogenes* by contacting artificially contaminated food samples with a bacteriophage modified to express a reporter gene specific for *Listeria monocytogenes*. The bacteriophage infects the *Listeria monocytogenes* cells, causing expression of the reporter gene.

Claim 1 as pending in the present invention is as follows (emphasis added):

1. A method for evaluating whether a implantable material will allow modified living bacteria to pass through the implantable material or around the implantable material or into the implantable material comprising:

- a) providing **living bacteria which are modified to produce a first detectable signal**;
- b) placing the **modified living bacteria** on a first side of the implantable material being evaluated; and
- c) detecting whether the first signal is present on a second side of the implantable material or within the implantable material;

where absence of the first signal on the second side of the implantable material or within the implantable material indicates that the **modified living bacteria** have not passed through or around the implantable material and where presence of the first signal on the second side of the implantable material or within the implantable material indicates that the modified living bacteria have passed through or around the implantable material; and  
where the implantable material is non-living.

Loessner et al. does not appear to disclose “living bacteria which are modified to produce a first detectable signal” for any purpose whatsoever. As can be appreciated, the method in Loessner et al. requires providing a modified bacteriophage to infect the bacteria in the contaminated sample. Hence, Loessner et al. does not anticipate claim 1.

Claims 2, 4, 7 and 11 depend on claim 1. Therefore, the Applicant requests that the rejection of claims 1, 2, 4, 7 and 11 under 35 U.S.C. §102(b) be withdrawn.

**With Respect to the Rejections under 35 U.S.C. §103(a), Paragraph 7 of the Outstanding Office Action:**

Claims 1-8 and 11 stand rejected under 35 U.S.C. §103(a) as being obvious over United States Patent 5,736,351 to Miller in view of Contag et al. Contag et al., discloses a method for detecting bacterial pathogens in a living host by inoculating the host intraperitoneally with a modified pathogen and determining the distribution of the pathogen after inoculation. Claims 1-3, 9 and 10, have been amended to stress that the present method is limited to “a method for evaluating ...an implantable material.”

Further, trying either disclosed method of Miller in combination with the disclosed method of Contag et al. would render each disclosed methods not functional. Hence, there is no motivation to combine the disclosure of Miller and Contag et al.

Therefore, the Applicant requests that the rejection of claims 1-8 and 11 under 35 U.S.C. §103(a) be withdrawn.

**With Respect to the Rejections under 35 U.S.C. §103(a), Paragraph 8 of the Outstanding Office Action:**

Claims 9 and 12 stand rejected under 35 U.S.C. §103(a) as being obvious over United States Patent 5,736,351 to Miller in view of Contag et al. and further in view of United

States Patent 5,814,331 to Holen. Claims 9 and 12 depend on claim 1. As discussed above, claim 1 is believed to be in condition for allowance. Therefore, this rejection is moot.

### CONCLUSION

The Applicants believe that all pending claims, claims 1-12, and 23-32 are now in condition for allowance and an indication of such is requested. If, however, there remain any issues which can be addressed by telephone, the Examiner is encouraged to contact the undersigned.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication to Deposit Account No. 19-2090.

Respectfully submitted,

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